

al., Cottle, McKay and Gross et al., is considered a matter of obvious design choice to one of ordinary skill in the art as well as specific dimensioning. The Examiner further states that the steps of method claims 3-4 and 24, would be obvious in view of the references applied. A brief analysis of each of the references relied on by the Examiner appears in the Response filed on October 27, 1999, to the first office action dated September 20, 1999, and is not repeated herein.

At page 3 of the Office Action, the Examiner responds to the arguments made by the Applicant. Responsive to Applicant's argument that the references do not teach or suggest a bone allograft as presently claimed, by stating that this argument is not persuasive since both Senter et al. and Heggeness et al. teach as part of the prior art allografts of an inherent shape with Heggeness et al. teaching that the allografts may be produced in a variety of shapes and sizes. The Examiner concludes that the known shapes of similar implants such as shown by the secondary references, would be produced and obvious and/or known to a person of ordinary skill in the art. In view of the following, this rejection is respectfully traversed.

Again, it is submitted that the Examiner has not established a proper case of *prima facia* obviousness. A proper case of *prima facia* obviousness under 35 U.S.C. § 103, requires that the prior art as a whole, must suggest the desirability of making the claimed combination and provide a reasonable expectation of success.

The Examiner states that Senter et al. and Heggeness et al. teach that allografts are part of the known prior art, and that these allografts have an inherent shape. Senter et al. teaches a ceramic implant having a pattern of serrations on its face. Heggeness et al. teach an implant composed of metal, metal alloy, or ceramics. Senter et al. at col. 2, lines 17-23, states that "Other options for a graft source for the implant are bone removed from cadavers, termed an allograft,...In these cases, ...there is the increased difficultly with graft rejection and the risk of transmitting communicable diseases." Heggeness et al. at col. 1, lines 44-57, state that allografts can be produced in a variety of sizes and shapes. Neither of the references suggest a particular size of shape suitable for an allograft implant. In fact, both references *teach away* from the use of an allograft implant. Senter et al. state that allograft implants exhibit increased difficulty with graft rejection and increased risk

of transmitting communicable diseases. Heggeness et al. state that the prior art devices including allograft implants, are not designed to accommodate the defined anatomical contours of the vertebral endplate, and that consequently, these devices contact only a minimal number of points on the surface of the vertebral endplates. Heggeness et al. state that such an uneven distribution of stress exerted by adjacent vertebrae upon the devices further results in an increased risk of subsidence and collapse of the device. See col. 2, lines 45-51. Heggeness et al. also state that bone grafts do not always heal reliably, and have reported failure rates of 10% to 40%, and that without complete bone fusion of the vertebral endplates with the intervertebral device or graft, the vertebrae adjacent to the device or graft is less stable, often necessitating further surgery.

As discussed in the response filed on October 27, 1999, the law on *teaching away* is clear and must be considered. Again, the court in *In re Dow Chemical Co.*, 837 F.2d 469, 5 USPQ2d 1529 (Fed. Cir. 1988) held in reference to obviousness, that: "...In determining whether such a suggestion can fairly be gleaned from the prior art, the full field of the invention must be considered for the person of ordinary skill is charged with the knowledge of the ...including that which might lead away from the claimed invention." The court in *In re Gurley*, 27 F.3d 551, 31 USPQ2d 1130 (Fed. Cir. 1994) held that "A prior art reference may be said to *teach away* when a person of ordinary skill; upon reading the reference, would be discouraged from following the path set out in the reference, or would be led in a direction divergent from the path that was taken by the applicant." The court in *Bausch & Lomb, Inc. v. Barnes-Hind/Hydrocurve, Inc.*, 796 F.2d 443, 230 USPQ 416 (Fed. Cir. 1986), held that "A reference should be considered as a whole, and portions arguing against or teaching away from the claimed invention must be considered.

At page 3, of the office action, the Examiner acknowledges that "obviousness can only be established by combining or modifying the teachings of the prior art to produce the claimed invention where there is some teaching, suggestion, or motivation to do so found either in the references themselves or in the knowledge generally available to one of ordinary skill in the art. The Examiner then states on page 4 of the office action, that both Senter et al. and Heggeness et al. teach prior art of known bone allograft with Senter et al showing an implant 50 inclusive of what may be termed protrusions and with Heggeness et al. stating that allografts may be made in various shapes and sizes.

The Examiner concludes that the combination of these teachings with known prior art shapes is believed obvious to a person of ordinary skill in the art, and further in view of Heggeness et al. the specific shape is one of obvious design choice. The Examiner has not addressed Applicant's arguments regarding *teaching away*.

The fact that both Senter et al. and Heggeness et al. may teach that allograft implants are known in the prior art, does not negate the fact that these references teach that such allograft implants are undesirable. Neither of these references, nor any of the other references, provide any suggestion whatsoever to produce an allograft implant, let alone the specifically claimed implant. The fact that Heggeness et al. state that allografts may be made in various shapes and sizes does not negate the fact that Heggeness et al. teach that such allografts are undesirable, and does not suggest the presently claimed implant. The fact that all of the references *teach away* from an allograft implant, must be considered by the Examiner. Thus, in view of this "*teaching away*" and the fact that all of the references are directed to synthetic implants, the references do not provide any "teaching, suggestion, or motivation" to "combine or modify" their teachings to arrive at the claimed invention.

Assuming *arguendo*, that some teaching, motivation, or suggestion, did exist, at most, the Examiner has only established that it would be "obvious to try," because there is no reasonable expectation of success. There is no reasonable expectation of success because none of the references taken alone or together teach or suggest that allograft material could be expected to behave similar to a synthetic material. None of the references suggest, for example, that allograft bone possesses mechanical properties similar to those of the reference material, or that allograft material could achieve the desired result. In fact the references clearly teach that allograft bone is not similar and is not sufficient since the use of allograft bone results in increased incidence of infection, graft rejection, inadequate support, collapse of the implant, etc, all of which ultimately affect the properties including the mechanical properties, of the implant. Please see the arguments presented on pages 3 and 4 of the response filed on October 27, 1999, responsive to the first office action issued in the above-identified application.

In view of the references, it is submitted that one of ordinary skill in the art would not be motivated to even investigate allograft material as a source for implant material and in fact would be

led away from doing so by the teachings of the references, and that even if such investigation were undertaken, there would be no expectation of success since bone material and synthetic materials are vastly different and exhibit vastly different properties including mechanical properties.

In view of the above, it is submitted that a proper case of prima facie obviousness has not been established, and that nothing in any of the cited references, taken alone or together, suggest claims 1-26 within the meaning of 35 U.S.C. § 103. Accordingly, the examiner is respectfully requested to withdraw this rejection.

It is submitted that claims 1-26 are in condition for immediate allowance and early notice to that effect is respectfully requested. The Examiner is invited to contact the undersigned at her Virginia Beach, Virginia telephone number on any questions that may arise.

Respectfully submitted,
LIFENET



Susanne M. Hopkins
Attorney for Applicant
Registration no: 33,247

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LIFENET
5809 Ward Court
Virginia Beach, Virginia 23455
Phone: (757) 464-4761
Fax: (757) 464-5721